FOAMING HAND SANITIZER - benzalkonium chloride gel
TOPCO ASSOCIATES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

ACTIVE INGREDIENT

BENZALKONIUM CHLORIDE 0.1 PERCENT

PURPOSE

ANTIMICROBIAL

USES

TO HELP REDUCE BACTERIA ON THE SKIN THAT COULD CAUSE DISEASE. RECOMMENDED FOR REPEATED USE.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

PUMP ENOUGH PRODUCT TO YOUR PALM TO THOROUGHLY COVER YOUR HANDS, RUB TOGETHER UNTIL DRY.

QUESTION OR COMMENTS

1-888-423-0139

INACTIVE INGREDIENTS

WATER, POLYSORBATE 20, ETHYLHEXYL METHOXYCINNAMATE, BUTYL METHOXYDIBENZOYLMETHANE, ETHYLHEXYL SALICYLATE, PPG-26-BUTETH-26, PEG-40 HYDROGENATED CASTOR OIL, ALOE BARBADENSIS LEAF JUICE, FRAGRANCE, TETRASODIUM EDTA, DMDM HYDANTOIN, SODIUM HYDROXIDE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

FOAMING HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-240
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
AVOBENZONE (UNII: G63QQF2NOX)	
OCTISALATE (UNII: 4X49Y0596W)	
CASTOR OIL (UNII: D5340Y2I9G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
EDETATE SODIUM (UNII: MP1J8420LU)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-240-08	236 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/23/2011	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 6/2011 TOPCO ASSOCIATES LLC